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| APPLICATION NO.   | FILING DATE               | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------------------|----------------------|---------------------|------------------|
| 10/539,814  | 06/20/2005                | Kevin P Granata      | 00852-03            | 5034             |
| 34444 7590 03/02/2010<br>UNIVERSITY OF VIRGINIA PATENT FOUNDATION |                           | EXAMINER             |                     |                  |
| 250 WEST MAIN STREET, SUITE 300                                   |                           |                      | NGUYEN, HUONG Q     |                  |
| CHARLOTTES  | CHARLOTTESVILLE, VA 22902 |                      | ART UNIT            | PAPER NUMBER     |
|   |                           |                      | 3736                |                  |
|   |                           |                      |                     |                  |
|   |                           |                      | MAIL DATE           | DELIVERY MODE    |
|   |                           |                      | 03/02/2010          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s)  |  |  |  |  |
|--|---|---|--|--|--|--|
|  | 10/539,814  | GRANATA ET AL.  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit  |  |  |  |  |
|  | HELEN NGUYEN  | 3736  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c  | orrespondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | lely filed the mailing date of this communication. (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |   |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>09 De</u>   | ecember 2009.   |   |  |  |  |  |
|  | action is non-final.  |   |  |  |  |  |
| ·=   | <i>7</i> <b>-</b>   |   |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |   |  |  |  |  |
| Disposition of Claims  |   |   |  |  |  |  |
| 4)⊠ Claim(s) <u>1-36</u> is/are pending in the application.  |   |   |  |  |  |  |
|  | 4a) Of the above claim(s) <u>1-15</u> is/are withdrawn from consideration.  |   |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |   |  |  |  |  |
| 6)⊠ Claim(s) <u>16-36</u> is/are rejected.   |   |   |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |   |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  | 8) Claim(s) are subject to restriction and/or election requirement.   |   |  |  |  |  |
| Application Papers   |   |   |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.  |   |   |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>20 June 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.  |   |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |   |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |   |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |   |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |   |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |   |  |  |  |  |
|  |   |   |  |  |  |  |
| Attachment(s)  |   |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary  |   |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application  |   |   |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  6) Other:   |   |   |  |  |  |  |

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### **DETAILED ACTION**

### Election/Restrictions

- 1. Applicant's election of Group II in the reply filed on 12/9/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election *without traverse* (MPEP § 818.03(a)).
- 2. Claims 1-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
- 3. Claims 16-36 remain under prosecution.

# **Priority**

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority to provisional application # 60/435137, filed on 12/20/2002.

## Information Disclosure Statement

- 5. It is noted that Applicant has not submitted an Information Disclosure Statement (IDS). Applicant is reminded of the duty to disclose all known prior art resulting for any and all prior art searches.
- 6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be

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incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. This refers to the references disclosed on p.3-4 of Applicant's specification.

## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. **Claims 16-21, 24-25, and 27-30** are rejected under 35 U.S.C. 102(b) as being anticipated by Girone et al (US Pat No. 6162189).
- 9. In regards to **Claim 16**, Girone et al disclose a device capable of assessing musculoskeletal dynamics of a joint of a patient in a weight-bearing posture, comprising: a) a platform 12, 25, 29 to support a patient in a weight-bearing posture, best seen in Figure 1-2A and 14A; b) a drive mechanism 30 to impart pulse movement to said platform, best seen in Figure 2A and 4 (Col.5: 40-63); c) a position sensor 44 to sense a position of said platform (Col.6: 4-12); d) a force or torque sensor 36 to sense a force or torque on said platform (Col.5: 29-33); e) a control system 14, 18 capable of determine musculoskeletal dynamics based on outputs from said displacement sensor and said force or torque sensor (displacement data 49 and force data 39 both feed into control system 14), best seen in Figure 5 (Col.6: 14-17).

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10. In regards to **Claim 17**, said musculoskeletal dynamics includes inertia (weight) (Col.13: 51-52).

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- 11. In regard to **Claims 18-21**, the device of Girone et al is capable of calculating musculoskeletal dynamic parameters such as damping, neuro-mechanical resistance to rotational velocity, stiffness, and neuro-mechanical resistance to ankle rotational angle.
- 12. In regards to **Claim 24**, said control system 14, 18 includes a computer capable of being programmed to determine values of inertia, resistance and stiffness based on data from the position sensor 44 and the force or torque sensor 36, wherein it is known in the art that such values can be calculated from position and force/torque.
- 13. In regards to **Claim 25**, said drive mechanism 30 is controlled and capable of imparting a random or pseudorandom series of pulses of movement (Col.10: 2-42).
- 14. In regards to **Claims 27-28**, said drive mechanism 30 is controlled via a control device 14, 18 which includes a programmed computer.
- 15. In regards to **Claims 29-30**, a control device 18 of the control system for determining musculoskeletal dynamics is independent from said control device that controls said drive mechanism. Similarly, a control device 14 of the control system for determining musculoskeletal dynamics may be the same as said control device that controls said drive mechanism 30 (Col.9: 50-67).
- 16. Claims 16-21 and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Allum (US Pat No. 56063046).

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- 17. In regards to **Claim 16**, Allum discloses a device capable of assessing musculoskeletal dynamics of a joint of a patient in a weight-bearing posture, comprising: a) a platform 26 to support a patient in a weight-bearing posture, best seen in Figure 2; b) a drive mechanism 58 to impart pulse movement to said platform (Col.11: 16-58); c) a position sensor to sense a position of said platform (Col.11: 59-Col.12: 18); d) a force or torque sensor 82 to sense a force or torque on said platform (Col.12: 21-27); e) a control system 24 capable of determine musculoskeletal dynamics based on outputs from said displacement sensor and said force or torque sensor, best seen in Figure 1.
- 18. In regard to **Claims 17-21 and 24**, the device of Allum is capable of calculating musculoskeletal dynamic parameters such as includes inertia, damping, neuro-mechanical resistance to rotational velocity, stiffness, and neuro-mechanical resistance to ankle rotational angle.
- 19. In regards to **Claim 25**, Allum disclose said drive mechanism 58 is controlled and capable of imparting a random or pseudorandom series of pulses of movement.

  In regards to **Claim 26**, Allum disclose said drive mechanism 58 includes an electric motor (Col.11: 21).
- 20. In regards to **Claims 27-30**, said drive mechanism 58 is controlled via a control device 24 which includes a programmed computer (Col.14: 66-67).

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# Claim Rejections - 35 USC § 103

- 21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 22. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girone et al or Allum.
- 23. Girone et al or Allum disclose the invention above but do not disclose said control system is configured to determine values of I, b or k based on data from the position sensor and the force or torque sensor in accordance with the formula of Claim 22. However, it is obvious to one of ordinary skill in the art that the control system of Girone et al or Allum would use the above formula and determine the values of inertia, resistance, and stiffness based upon the position sensor and force or torque sensor data because a skilled artisan would recognize that said variables may be mathematically correlated with position and force or torque.
- 24. Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allum (US Pat No. 56063046) in view of Greenbaum (US Pat No. 5483825).
- 25. In regards to **Claim 31**, Allum et al disclose a device capable of assessing musculoskeletal dynamics of a body part of a patient in a weight-bearing posture, comprising: a) a platform 26 that supports a patient in a weight-bearing posture, best seen in Figure 2; b) said platform being rotatably supported to rotate around an axis 50, 54 through said body part

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(Col.10: 43-67); c) a drive mechanism 58 that is capable of imparting a plurality of pulses to said platform at durations of less than about 50 milliseconds and at intervals of less than about 100 milliseconds (Col.11: 16-58); d) an angle sensor that senses an angular position of said platform (Col.11: 59-Col.12: 18); e) a force sensor 82 that senses a force at said platform such that ankle torque may be determined (Col.12: 21-26); f) computer 24 and digital data storage 28 capable of storing angle and force time-based data from said angle and force sensors, best seen in Figure 1.

26. However, Allum does not explicitly disclose the force sensor is a torque sensor.

However, it is well known in the art that torque sensors directly measure the torque of a desired object. For example, Greenbaum teaches that ankle torque sensor 62 is used to directly measure ankle torque (Col.3: 18-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the force sensor of Allum with a torque sensor to directly measure the ankle torque at said platform.

- 27. In regards to **Claim 32**, Allum discloses at least one control system 24 to control said drive mechanism 58 (Col.14: 66-Col.15: 3) and is capable of determining musculoskeletal dynamics based on said data in said digital data storage.
- 28. In regards to **Claim 33**, said device of Allum is capable of assessing musculoskeletal dynamics of a patient's ankle in a weight-bearing upright standing posture and with the ankle rotating in an inversion and/or eversion direction upon said platform (Col.10: 60-64).
- 29. In regards to **Claims 34-36**, said angle and torque time-based data obtained from said angle and torque sensors of Allum as modified above is capable of including at least about 10

data points per second, at least about 20 data points per second, or at least about 100 data points per second.

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- 30. Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girone et al in view of Allum.
- 31. In regards to Claim 31, Girone et al disclose a device capable of assessing musculoskeletal dynamics of a body part of a patient in a weight-bearing posture, comprising: a) a platform 12, 25, 29 that supports a patient in a weight-bearing posture, best seen in Figure 1-2A and 14A; c) a drive mechanism 30 that is capable of imparting a plurality of pulses to said platform at durations of less than about 50 milliseconds and at intervals of less than about 100 milliseconds best seen in Figure 2A and 4 (Col.4: 52-55; Col.5: 40-63); e) a force sensor 36 that senses a torque at said platform (Col.5: 29-33); f) computer 18 necessarily having digital data storage capable of storing data from at least the force sensor.
- 32. However, Girone et al do not explicitly disclose the force sensor is a torque sensor. However, it is well known in the art that torque sensors directly measure the torque of a desired object. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the force sensor of Girone et al with a torque sensor to directly measure the torque on said platform (abst).
- 33. However, Girone et al while disclosing said platform has degrees of freedom, does not explicitly disclose said platform being rotatably supported to rotate around an axis through said body part. It is also noted that Girone et al provide a position sensor 44 to sense the position of

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the platform. Allum teaches an analogous platform 26 that supports a patient in a weight bearing posture, best seen in Figure 2, said platform being rotatably supported to rotate around an axis 50, 54 through said body part (Col.10: 43-67), as well as a drive mechanism 58 that is capable of imparting a plurality of pulses to said platform at durations of less than about 50 milliseconds and at intervals of less than about 100 milliseconds (Col.11: 16-58), and an angle sensor that senses an angular position of said platform (Col.11: 59-Col.12: 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the platform of Girone et al be rotatably supported to rotate around an axis through said body part as well as include an angle sensor to sense the angular position of said platform as taught by Allum, to effectively provide input regarding the angular position of the platform as a result of a entire range of movement of the body part including rotational movement on the platform.

- 34. In regards to **Claim 32**, Girone et al disclose at least one control system 14 to control said drive mechanism 30 and is capable of determining musculoskeletal dynamics based on said data in said digital data storage.
- 35. In regards to **Claim 33**, said device of Girone et al in combination with Allum is capable of assessing musculoskeletal dynamics of a patient's ankle in a weight-bearing upright standing posture and with the ankle rotating in an inversion and/or eversion direction upon said platform.
- 36. In regards to **Claims 34-36**, said angle and torque time-based data obtained from said angle and torque sensors of Girone et al as modified by Allum is capable of including at least about 10 data points per second, at least about 20 data points per second, or at least about 100 data points per second.

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Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340.

The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

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